

EXHIBIT E

From: [Strahorn, Suzanne](#)
 To: [Mather, Mandiehl](#); [Aunne, Linda](#)
 Cc: [Ryer, Julie](#)
 Date: Monday, June 13, 2022 8:24:48 AM
 Re: [RE: BLA 761144 communications](#)

Hi Mandiehl,

In the table below if there is "Electronic" or "Mail" in the column titled "Sent Via" this represents a communication sent to Cytodyn. N/A in this column would be an internal communication. Blank areas are incoming submissions from Cytodyn.

I hope this helps.
 Suzanne

From: Mather, Mandiehl <[Mandiehl.Mather@fda.hhs.gov](#)>
 Sent: Friday, June 10, 2022 9:08 PM
 To: Strahorn, Suzanne <[Suzanne.Strahorn@fda.hhs.gov](#)>; Aunne, Linda <[Linda.Aunne@fda.hhs.gov](#)>
 Cc: Ryer, Julie <[Julie.Ryer@fda.hhs.gov](#)>
 Subject: RE: BLA 761144 communications

Thanks, Suzanne. This is very helpful. Are these communications FROM FDA to Cytodyn? Linda sent me a link to the DARRTS download, but I only had the communications FROM Cytodyn to FDA.

From: Strahorn, Suzanne <[Suzanne.Strahorn@fda.hhs.gov](#)>
 Sent: Friday, June 10, 2022 5:03 PM
 To: Mather, Mandiehl <[Mandiehl.Mather@fda.hhs.gov](#)>; Aunne, Linda <[Linda.Aunne@fda.hhs.gov](#)>
 Cc: Ryer, Julie <[Julie.Ryer@fda.hhs.gov](#)>
 Subject: RE: BLA 761144 communications

Some good news – there are no communications in CARTRs for BLA 761144 from 2018 as this did not open (first submission) until March 15, 2019.

I figured how this was set-up for you but there are numerous 2018 communications in DARRTS that can be pulled?

Supporting Document Number/Communication Author	eCTD Sequence Number	Received / Communication Date	Sent Via	Submit / Final Date	Supporting Document Category/Subcategory / Communication Function	Submission Type/Submission Classification	Archive/EDR
259	254	1/9/2019		1/9/2019	Clinical/Response To Information Request	Original-1	EDR
WIMSTOCK, KAREN D		12/28/2018	ELECTRONIC	12/28/2018	COR-INDAQ-02 (Advice/Information Request)	Original-1	Archive
STRAHORN, SUZANNE K		12/21/2018	ELECTRONIC	12/21/2018	COR-INDAQ-02 (Advice/Information Request)	General Information-1	Archive
256	253	12/28/2018		12/28/2018	Pediatric Study Plan/Pediatric Study Plan - Other	Pediatric Study Plan-1 (Initial)	EDR
257	252	12/22/2018		12/22/2018	Pediatric Study Plan/Pediatric Study Plan - Re-submission	Pediatric Study Plan-1 (Initial)	EDR
STRAHORN, SUZANNE K		12/17/2018	ELECTRONIC	12/17/2018	COR-INDAQ-02 (Advice/Information Request)	General Information-1	Archive
256	251	12/4/2018		12/4/2018	Quality/Response To Information Request	Original-1	EDR
STRAHORN, SUZANNE K		11/9/2018	ELECTRONIC	11/9/2018	COR-INDAQ-02 (Advice/Information Request)	General Information-1	Archive
CHADHURY, AZEEM D		11/9/2018	MAIL	11/9/2018	COR-HF-2 (Human Factors Validation Study Protocol Advice)	Original-1	Archive
255	250	11/26/2018		11/26/2018	Clinical Pharmacology/Response To Information Request	Original-1	EDR
VAUGHAN, VALERIE S		11/21/2018	N/A	11/21/2018	REV-SURVEY-32 (Human Factors Validation Protocol)	Original-1	Archive
STRAHORN, SUZANNE K		11/19/2018	ELECTRONIC	11/19/2018	COR-INDAQ-02 (Advice/Information Request)	Original-1	Archive
MOJIB, AUCIA		11/19/2018	ELECTRONIC	11/19/2018	COR-INDAQ-02 (Advice/Information Request)	Original-1	Archive
254	249	11/8/2018		11/8/2018	Rolling Submission/Rolling Review Designation Request	General Information-1	EDR
253	248	11/7/2018		11/7/2018	Non-Clinical/Response To Information Request	Original-1	EDR
STRAHORN, SUZANNE K		11/6/2018	MAIL	11/6/2018	COR-PSP-02 (Pediatric Study Plan - Incomplete)	Pediatric Study Plan-1 (Initial)	Archive
STRAHORN, SUZANNE K		11/6/2018	ELECTRONIC	11/6/2018	COR-INDAQ-02 (Advice/Information Request)	Original-1	Archive
STRAHORN, SUZANNE K		11/6/2018	N/A	11/6/2018	CONSULT-REV-NONCDER-06 (Consult Review from CDER)	Original-1	Archive
STRAHORN, SUZANNE K		11/6/2018	N/A	11/6/2018	FRM-CONSULT-02 (Intercenter/Combination Products Consult)	Original-1	Archive
STRAHORN, SUZANNE K		11/6/2018	ELECTRONIC	11/6/2018	COR-INDAQ-02 (Advice/Information Request)	Original-1	Archive
252	247	11/6/2018		11/6/2018	Clinical/Response To Information Request	Original-1	EDR
251	246	10/29/2018		10/29/2018	Pediatric Study Plan/Initial Pediatric Study Plan	Pediatric Study Plan-1 (Initial)	EDR
DUBVION, JOHN H		10/24/2018	N/A	10/24/2018	REV-NONCLINICAL-21 (Primary Review), REV-NONCLINICAL-21 (Primary Review)	General Information-1, Original-1	Archive
MILLS SHARON R		10/23/2018	N/A	10/23/2018	CONSULT-TRN-PUREV-31 (Patient Labeling Review)	Original-1	Archive
STRAHORN, SUZANNE K		10/22/2018	ELECTRONIC	10/22/2018	COR-INDAQ-02 (Advice/Information Request)	General Information-1	Archive
250	245	10/17/2018		10/17/2018	Clinical/Response To Information Request	Original-1	EDR
CHADHURY, AZEEM D		10/10/2018	N/A	10/10/2018	FRM-CONSULT-26 (Patient Labeling Consult Request)	Original-1	Archive
249	244	10/5/2018		10/5/2018	Quality/Response To Information Request	Original-1	EDR
248	243	10/4/2018		10/4/2018	Quality/Response To Information Request - Clinical Pharmacology/Response To Information Request	Original-1	EDR
247	242	10/9/2018		10/9/2018	Human Factors/Response To Information Request	Original-1	EDR
TAUBER, WILLIAM B		10/9/2018	N/A	10/9/2018	REV-CLIN CAL-21 (Primary Review)	Original-1	Archive
CHADHURY, AZEEM D		9/26/2018	ELECTRONIC	9/26/2018	COR-INDAQ-02 (Advice/Information Request)	Original-1	Archive
246	241	9/14/2018		9/14/2018	Human Factors Protocol, Human Factors/Use-Related Risk Analysis	Original-1	Archive
TAUBER, WILLIAM B		9/10/2018	N/A	9/10/2018	REV-CLIN CAL-21 (Primary Review)	Original-1	Archive
NAEGER, LISA K		9/10/2018	N/A	9/10/2018	REV-CLIN MICRO-21 (Primary Review)	Original-1	Archive
DUBVION, JOHN H		9/22/2018	N/A	9/22/2018	REV-NONCLINICAL-21 (Primary Review)	Original-1	Archive
HONG, MYUNG JOOP		9/22/2018	ELECTRONIC	9/22/2018	COR-INDAQ-02 (Advice/Information Request)	Original-1	Archive
HONG, MYUNG JOOP		9/21/2018	ELECTRONIC	9/21/2018	COR-INDAQ-02 (Advice/Information Request)	Original-1	Archive
SUN, HENGJUN N		9/21/2018	N/A	9/21/2018	REV-BIOMETRICS-21 (Primary Review)	Original-1	Archive
245	240	9/5/2018		9/5/2018	Clinical/Response To Information Request	Original-1	EDR
244	239	9/5/2018		9/5/2018	Clinical/Consent Forms Protocol/New Clinical Protocol	Original-1	EDR
STRAHORN, SUZANNE K		9/7/2018	ELECTRONIC	9/7/2018	COR-INDAQ-02 (Advice/Information Request)	Original-1	Archive
243	238	9/7/2018		9/7/2018	New/Annual Report	Annual Report-14	EDR
TAUBER, WILLIAM B		9/1/2018	N/A	9/1/2018	REV-CLIN CAL-21 (Primary Review)	Original-1	Archive
TAUBER, WILLIAM B		7/24/2018	N/A	7/24/2018	REV-CLIN CAL-21 (Primary Review)	Original-1	Archive
STRAHORN, SUZANNE K		7/24/2018	ELECTRONIC	7/24/2018	COR-INDAQ-02 (Advice/Information Request)	General Information-1	Archive
STRAHORN, SUZANNE K		7/24/2018	ELECTRONIC	7/24/2018	COR-INDAQ-02 (Advice/Information Request)	General Information-1	Archive
STRAHORN, SUZANNE K		7/18/2018	MAIL	7/18/2018	COR-MEET-03 (Meeting Minutes), COR-MEET-03 (Meeting Minutes)	Original-1, General Information-1	Archive
242	237	7/12/2018		7/12/2018	Protocol/Change, Clinical/Consent Forms	Original-1	EDR
JOHNSON, SARAH A		7/6/2018	N/A	7/6/2018	REV-QUALITY-21 (Primary Review)	General Information-1	Archive
SUN, HENGJUN N		6/22/2018	N/A	6/22/2018	REV-BIOMETRICS-21 (Primary Review)	General Information-1	Archive
TAUBER, WILLIAM B		6/22/2018	N/A	6/22/2018	REV-CLIN CAL-21 (Primary Review)	Original-1	Archive
NAEGER, LISA K		6/22/2018	N/A	6/22/2018	REV-CLIN MICRO-21 (Primary Review), REV-CLIN MICRO-21 (Primary Review)	General Information-1, Original-1	Archive
HSU, CHH-JUNG		6/19/2018	N/A	6/19/2018	REV-QUALITY-21 (Primary Review)	Original-1	Archive
HSU, CHH-JUNG		6/19/2018	N/A	6/19/2018	REV-QUALITY-21 (Primary Review)	Original-1	Archive
STRAHORN, SUZANNE K		6/16/2018	ELECTRONIC	6/16/2018	COR-MEET-06 (Meeting - Preliminary Comments), COR-MEET-06 (Meeting - Preliminary Comments)	General Information-1, Original-1	Archive
241	236	6/7/2018		6/7/2018	Clinical/Response To Information Request	Original-1	EDR
STRAHORN, SUZANNE K		6/6/2018	ELECTRONIC	6/6/2018	COR-INDAQ-02 (Advice/Information Request), COR-INDAQ-32 (Advice/Information Request)	Original-1, General Information-1	Archive
STRAHORN, SUZANNE K		6/6/2018	MAIL	6/6/2018	COR-BREAK-03 (Deny/Breakthrough Therapy Designation), COR-BREAK-03 (Deny/Breakthrough Therapy Designation)	Original-1, General Information-1	Archive
STRAHORN, SUZANNE K		6/5/2018	ELECTRONIC	6/5/2018	COR-INDAQ-02 (Advice/Information Request), COR-INDAQ-32 (Advice/Information Request)	General Information-1, Original-1	Archive
TAUBER, WILLIAM B		5/29/2018	N/A	5/29/2018	REV-CLIN CAL-24 (Breakthrough Therapy Designation Determination)	General Information-1	Archive
240	235	5/29/2018		5/29/2018	Clinical/Response To Information Request	Original-1	EDR
239	234	5/24/2018		5/24/2018	Non-Clinical/Non-Clinical Information	Original-1	EDR
NAEGER, LISA K		5/22/2018	N/A	5/22/2018	REV-CLIN MICRO-21 (Primary Review)	General Information-1	Archive
238	233	5/18/2018		5/18/2018	Meeting/Meeting Package, Clinical/Response To Information Request	General Information-1, Original-1	EDR
STRAHORN, SUZANNE K		5/14/2018	ELECTRONIC	5/14/2018	COR-INDAQ-02 (Advice/Information Request)	General Information-1	Archive
STRAHORN, SUZANNE K		5/14/2018	ELECTRONIC	5/14/2018	COR-INDAQ-02 (Advice/Information Request)	General Information-1	Archive
TAUBER, WILLIAM B		5/11/2018	N/A	5/11/2018	REV-CLIN CAL-21 (Primary Review)	Original-1	Archive
SUN, HENGJUN N		5/9/2018	N/A	5/9/2018	REV-BIOMETRICS-21 (Primary Review)	General Information-1	Archive
237	232	5/6/2018		5/6/2018	Clinical/Response To Information Request	Original-1	EDR
STRAHORN, SUZANNE K		4/30/2018	MAIL	4/30/2018	COR-MEET-01 (Meeting Request Granted)	General Information-1	Archive
SUN, HENGJUN N		4/29/2018	N/A	4/29/2018	REV-BIOMETRICS-21 (Primary Review)	Original-1	Archive
STRAHORN, SUZANNE K		4/27/2018	ELECTRONIC	4/27/2018	COR-INDAQ-02 (Advice/Information Request), COR-INDAQ-32 (Advice/Information Request)	General Information-1, Original-1	Archive
SUN, HENGJUN N		4/19/2018	N/A	4/19/2018	REV-BIOMETRICS-21 (Primary Review)	Original-1	Archive
STRAHORN, SUZANNE K		4/17/2018	MAIL	4/17/2018	COR-BREAK-01 (Accelerate/Breakthrough Therapy Designation Request)	General Information-1	Archive
236	231	4/16/2018		4/16/2018	Meeting/Meeting Request	General Information-1	EDR
235	230	4/12/2018		4/12/2018	Breakthrough Therapy Designation Request	General Information-1	EDR
STRAHORN, SUZANNE K		4/9/2018	ELECTRONIC	4/9/2018	COR-INDAQ-02 (Advice/Information Request)	Original-1	Archive
234	229	4/9/2018		4/9/2018	Quality/Quality Information	Original-1	EDR
NAEGER, LISA K		4/2/2018	N/A	4/2/2018	REV-CLIN MICRO-21 (Primary Review)	Original-1	Archive
SHAH, MILLIE B		3/28/2018	N/A	3/28/2018	CONSULT-REV-SAFETY-11 (Medication Error Review)	Original-1	Archive
233	228	3/27/2018		3/27/2018	Protocol/New Clinical Protocol	Original-1	EDR
STRAHORN, SUZANNE K		3/22/2018	ELECTRONIC	3/22/2018	COR-INDAQ-02 (Advice/Information Request)	General Information-1	Archive
232	227	3/18/2018		3/18/2018	Quality/Quality Information	Original-1	EDR
STRAHORN, SUZANNE K		3/16/2018	MAIL	3/16/2018	COR-MEET-04 (Meeting Request Withdrawn/Cancelled)	General Information-1	Archive
231	226	3/12/2018		3/12/2018	Meeting/Other	General Information-1	EDR
STRAHORN, SUZANNE K		3/6/2018	N/A	3/6/2018	FRM-CONSULT-06 (OSE Consult (Except Proprietary Name Review))	Original-1	Archive
230	225	3/6/2018		3/6/2018	Clinical/Response To Information Request	Original-1	EDR
STRAHORN, SUZANNE K		3/6/2018	MAIL	3/6/2018	COR-MEET-06 (Meeting - Preliminary Comments)	General Information-1	Archive
STRAHORN, SUZANNE K		2/28/2018	ELECTRONIC	2/28/2018	COR-INDAQ-02 (Advice/Information Request)	Original-1	Archive
229	224	2/28/2018		2/28/2018	Meeting/Other	General Information-1	EDR
STRAHORN, SUZANNE K		2/16/2018	ELECTRONIC	2/16/2018	COR-INDAQ-02 (Advice/Information Request)	General Information-1	Archive
228	223	2/16/2018		2/16/2018	Biometrics/Biometrics Information	Original-1	EDR
STRAHORN, SUZANNE K		2/6/2018	ELECTRONIC	2/6/2018	COR-INDAQ-02 (Advice/Information Request)	Original-1	Archive
SUN, HENGJUN N		2/6/2018	N/A	2/6/2018	REV-BIOMETRICS-21 (Primary Review)	Original-1	Archive
NAEGER, LISA K		2/6/2018	N/A	2/6/2018	REV-CLIN MICRO-21 (Primary Review)	Original-1	Archive
227	222	2/2/2018		2/2/2018	Biometrics/Biometrics Information	Original-1	EDR
226	221	1/31/2018		1/31/2018	Clinical/Clinical Information	Original-1	EDR
225	220	1/26/2018		1/26/2018	Protocol/Change, Clinical/Consent Forms	Original-1	EDR
224	219	1/26/2018		1/26/2018	Protocol/Change, Clinical/Consent Forms	Original-1	EDR
223	218	1/26/2018		1/26/2018	Clinical/Consent Forms, Protocol/Change	Original-1	EDR
222	217	1/26/2018		1/26/2018	Protocol/Change	Original-1	EDR
221	216	1/22/2018		1/22/2018	Meeting/Meeting Package	General Information-1	EDR
STRAHORN, SUZANNE K		1/4/2018	MAIL	1/4/2018	COR-MEET-01 (Meeting Request Granted)	General Information-1	Archive

STRAYHORN, SUZANNE K		1/2/2018	ELECTRONIC	1/2/2018	COR-INDAD-02 (Adverse Information Request)	Original-1	Archive
STRAYHORN, SUZANNE K		12/27/2017	ELECTRONIC	12/27/2017	COR-INDAD-02 (Adverse Information Request)	General Information-1	Archive

From: Mather, Mandehi <Mandehi.Mather@fda.hhs.gov>
Sent: Friday, June 10, 2022 6:14 PM
To: Alume, Linda <Linda.Alume@fda.hhs.gov>
Cc: Strayhorn, Suzanne <Suzanne.Strayhorn@fda.hhs.gov>; Ryer, Julie <Julie.Ryer@fda.hhs.gov>
Subject: RE: BLA 761144 communications

Hi Linda,

Hope you are well. It's me again :)

Prosecutor is now asking for communications between FDA and CytoDyn/Amarex in 2018 for BLA 761144 and IND 013609 (HIV). I records I have previously requested were from 2019-Present. I was able to pull the communications from CytoDyn from the DABRTS download you provided. I, ut don't have communications coming from the FDA to CytoDyn/Amarex in 2018.

I am on leave next week, but I have cc'd Special Agent Julie Ryer. Please send the records to her if you have them available next week. Otherwise, I will be back on 05/20.

Thanks again for all your help!

From: Alume, Linda <Linda.Alume@fda.hhs.gov>
Sent: Wednesday, March 9, 2022 12:59 PM
To: Mather, Mandehi <Mandehi.Mather@fda.hhs.gov>
Cc: Strayhorn, Suzanne <Suzanne.Strayhorn@fda.hhs.gov>
Subject: BLA 761144 communications

The BLA incoming and outgoing (cover letters only) communications are in SharePoint

The IND will be populated hopefully by the end of today

[DAVE active projects - Home \(fda.gov\)](#)

Linda

Linda C. (Onaps) Alume, BSPh
Chief, Physical Management Staff

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